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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,637	02/12/2004	Osamu Kato	049400-5027	1776

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WASHINGTON, DC 20004

EXAMINER

HALL, DEANNA K

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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08/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/776,637	Applicant(s) KATO ET AL.	
	Examiner Deanna K. Hall	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "said lowered-layered tube is applied at least partly to said hollow tube body" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. It is unclear how many layers of tubes applicant is claiming at this point and whether or not the hollow tube corresponds to the upper tube and the main tube corresponds to the

lower tube. This confusion continues in claim 7 where it appears that applicant interchanges lower and outer and in claim 8 where it appears that applicant interchanges upper and outer. In claim 9 it appears that applicant is claiming a two segment tube (lower and upper) and a three segment tube (lower, upper and outer). Furthermore, the Examiner has interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sønderskov Klint (US 6,589,227) ("Klint") in view of Shiber (US 5,653,696).**

Klint shows: a plurality of metallic wires 5 cylindrically stranded to form a flexible tube 3, an inner surface of which forms a convex-concave structure represented by said metallic wires each formed semi-circular in cross section. Klint further shows the rigid-flexible property of the flexible tube 3 gradually changing in the lengthwise direction Col. 7, lines 14-25.

With reference to claim 4, Klint further shows the hollow tube body 3 being applied at least partly to a mono-layered main tube body 15, see Fig. 3.

Klint discloses the invention as substantially claimed (see above); however, Klint fails to disclose a leading distal end of said flexible tube being formed into a knife-edge circle configuration to provide a knife-edge circle front. Shiber, in the analogous art, teaches a flexible tube with a knife-edge circle front 22, 102, Figs. 24-26. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Klint with the knife-edge circle front as taught by Shiber for breaking through an occlusion. Shiber teaches an outwardly arcuated blade edge which diametrically decreases progressively as approaching outward, see Fig. 6.

6. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klint in view of Shiber further in view of Toro et al. (US 6,342,066) ("Toro").

The combination of Klint/Shiber discloses the invention as substantially claimed (see above). Further, Klint teaches the stranding direction of metallic wires to be mutually opposite C14 L47-52 and for the rigidity of the tube to progressively increase from the lower-layered tube to the upper-layered tube C7 L14-25. However, this combination fails to disclose a three-layered structure with a self-expansible stent mounted on the lower-layered tube with the stent released by means of the outer tube. Toro, in the analogous art, teaches a stent 18 mounted on the lower-layered tube 40 and released by means of the outer tube 26. Further, Toro teaches a manipulating portion 41 of the lower-layered tube 14 and upper-layered tube 16 being connected in a row to a handling section 26, see also C3 L50-60.

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With reference to claim 5, as best understood by the examiner, Toro further teaches an upper-layered tube 20 and a lower-layer tube 14, 16 slidably fitted onto a main tube body 40.

Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the combination of Klint/Shiber with the stent mounted on the lower-layered tube and released by means of the outer tube as taught by Toro for releasing the stent into a desired location of the targeted vessel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deanna K. Hall
Examiner
AU 3767

dkh



LOAN H. THANH
PRIMARY EXAMINER